DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 5, 2015

Sofradim Production
% Ms. Mary Mellows
Surgical solutions, a global business unit of Covidien
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K150091
Trade/Device Name: Versatex™ Monofilament Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: April 21, 2015
Received: April 22, 2015

Dear Ms. Mellows:

This letter corrects our substantially equivalent letter of May 26, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150091

Device Name
Versatex™ Monofilament Mesh

Indications for Use *(Describe)*
Versatex™ Monofilament Mesh is intended for the repair of abdominal wail hemias or other fascial deficiencies that require the addition of a reinforcing material.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Information

Name	Sofradim Production (subsidiary of Covidien LLC)
Address	116, avenue du Formans 01600 Trevoux, France
Phone number	+33 (0) 4 74 08 90 00
Fax number	+33 (0) 4 74 08 90 02
Establishment Registration	9615742
Name of contact person	Mary Mellows Senior Regulatory Specialist Covidien 60 Middletown Avenue North Haven, CT 06473 Phone: (203) 492-5284 Fax: (203) 492-5029
Date prepared	January 15, 2015

Name of device

Trade or proprietary name	Versatex™ Monofilament Mesh
Common or usual name	Surgical Mesh
Classification name	Mesh, Surgical, Polymeric
Classification panel	General and Plastic Surgery (79)
Regulation	21 CFR 878.3300
Product Code	FTL
Legally marketed devices to which equivalence is claimed	Mersilene™ Polyester Fiber Mesh – Preamendment device Symbotex™ Composite Mesh – K142908
Reason for 510(k) submission	To obtain market clearance of Versatex™ Monofilament Mesh.
Device description	Versatex™ Monofilament Mesh is made out of a macroporous three-dimensional monofilament polyester textile. Largest sizes include a green dyed monofilament polyester (D&C Green No. 6) marking that is positioned in the center of the textile to help center and orient the mesh.
Intended use of the device	Versatex™ Monofilament Mesh is intended for soft tissue reinforcement where weakness exists.
Indications for use	Versatex™ monofilament mesh is intended for the repair of abdominal wall hernias or other fascial deficiencies that require the addition of a reinforcing material.

Summary comparing the technological characteristics of the subject and predicate devices

The subject Versatex™ Monofilament Mesh is substantially equivalent to the predicate device Mersilene™ Polyester Fiber Mesh (Preamendment device) in terms of indications and design for the following technological characteristics:

- Polyester textile performance
- Design: flat sheet meshes with equivalent shapes and sizes.

The subject Versatex™ Monofilament Mesh is substantially equivalent to the predicate device Symbotex™ Composite Mesh (K142908) in terms of intended use and design for the following technological characteristics:

- Same polyester materials and textiles
- Design: flat sheet meshes with equivalent shapes and sizes.

Performance data

Bench testing has been conducted in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh issued March 2, 1999 to evaluate the performance characteristics of the subject Versatex™ Monofilament Mesh. The following mesh characteristics were assessed: mesh thickness, pore size, surface density, bursting strength, bursting distension, breaking strength, elongation at break, tear strength, suture strength.

The bench results demonstrate that the device is substantially equivalent to the primary predicate Mersilene™ Polyester Fiber Mesh (Preamendment device).

Versatex™ Monofilament Mesh has the same intended use as the primary predicate Mersilene™ Polyester Fiber Mesh (Preamendment device).

Versatex™ Monofilament Mesh is made out of materials that have been evaluated for biocompatibility in accordance with ISO 10993-1 for a permanent implant, a recognized standard by FDA (#2-179).

Versatex™ Monofilament Mesh shelf-life has been demonstrated by the stability results of the material and the ability of packaging to maintain the sterile barrier.

In conclusion, all testing demonstrates that the subject Versatex™ Monofilament Mesh is substantially equivalent to the predicate devices.